



STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
POLICY AND PROCEDURE MANUAL
POLICY AND PROCEDURE

CHAPTER

Policy/Legislation

NUMBER

6.18

EFFECTIVE DATE

March 8, 2006

SUBJECT

Institutional Review Board Policy and Procedure

Page 1 of 2

A. PURPOSE

The purpose is to establish the policy and procedure for the Department of Community Health (DCH) Institutional Review Board (IRB) to review all human subjects research that is sponsored by, or involves, the department.

B. REVISION HISTORY

Issued: March 8, 2006.

Revised: February 23, 2007 and May 21, 2010

C. DEFINITIONS

Human Subject is a living individual from whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

Research is (1) a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, or (2) a systematic collection or analysis of data with the intent to generate new knowledge.

Further definitions are contained in 45 CFR 46.102 and the Michigan Department of Community Health Institutional Review Board Procedures.

D. POLICY

It is the policy of the DCH IRB to review all human subjects research that is sponsored by the department, or is conducted by or under the direction of any employee or agent of this department in connection with his or her departmental responsibilities, or is conducted by or under the direction of any employee or agent of this department using any property or facilities of this department, or involves the department's non-public information to identify or contact human subjects or prospective subjects. If a research activity involves the use or disclosure of protected health information, as defined by the Health Insurance Portability and Accountability Act (HIPAA), HIPAA privacy policy and procedures must also be considered.

E. PROCEDURE

<i>Responsibility</i>	<i>Action</i>
The director of each bureau or office in DCH	Is responsible to ensure that a current member of the DCH IRB is consulted on any project in his or her jurisdiction that may involve human subjects research.
If the IRB member determines that a proposal is (or could be) human subjects research	The application materials specified in the DCH IRB Procedures shall be submitted to the department's IRB. The IRB must either exempt or approve the activity before it can begin.
The director of each bureau or office in DCH that is involved in human subjects research	Shall ensure that all IRB requirements are fulfilled, including prompt reporting of modifications to approved protocols, complaints, and adverse events. He or she shall ensure that approved projects are submitted for re-approval prior to the approval expiration date, if the project will continue past this date.



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F. REFERENCES

DCH IRB Procedures. 45 CFR Part 46 and 21 RF Part 50. The Belmont Report. HIPAA.

G. CONTACT

For additional information concerning this policy, contact the DCH Institutional Review Board.

RECOMMENDED BY:

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DATE:

5/26/10

APPROVED BY:

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5/27/10

Michigan Department of Community Health

Institutional Review Board Procedures

January 2011

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1. Applicability

The Michigan Department of Community Health (MDCH) has established an Institutional Review Board (IRB) to help ensure that human subject's research is carried out in accordance with the highest ethical standards and in an environment where those involved in the conduct or oversight of human subject's research understand their primary responsibility for protecting the rights, welfare, and autonomy of subjects.

MDCH has a Federal Wide Assurance (FWA00007331) with the United States Department of Health and Human Services (HHS) that requires compliance with regulations that protect human research subjects. This assurance commits MDCH to comply with the requirements of Title 45 Code of Federal Regulations Part 46 (45 CFR Part 46) including subparts B, C and D, 21 CFR 50 and 21 CFR 56 for all federally sponsored research, **and** also for all other human subject's research involving MDCH, regardless of sponsorship.

IRB review is required whenever an activity that involves the collection or analysis of data with the intent to generate new knowledge includes an intervention or interaction with living individuals and/or the collection of, release of, or access to, identifiable private information or biological specimens.

MDCH IRB review is required whenever such activity is:

- 1) Sponsored by the department, **or**
- 2) Conducted by or under the direction of any employee or agent of the department in connection with his or her institutional responsibilities, **or**
- 3) Conducted by or under the direction of any employee or agent of the department using any facility of the department, **or**
- 4) Involves the use of the department's nonpublic information to identify, **or** contact, human research subjects or prospective subjects.

MDCH is also considered engaged in human subject's research by virtue of subject accrual, transfer of potentially identifiable information, and/or provision of something of value such as material support (e.g., funds, identifiable data), co-authorship, intellectual property, or credits.

Human Subject Involvement

An activity that involves the collection or analysis of data, with the intent to generate new knowledge, but does not include an intervention or interaction with living individuals or the collection of, release of, or access to identifiable private information or biological specimens, may not need IRB review. A member of the MDCH IRB should be consulted if there is any doubt about whether or not human subjects are involved.

Research

If human subjects are involved, and the activity includes the collection or analysis of data designed to develop or contribute to new knowledge, IRB review is required. When MDCH is involved in the activity as outlined above, the MDCH IRB review is required regardless of whether or not another IRB will also review the activity. This is true even if the MDCH IRB has a formal agreement with another IRB that allows the MDCH IRB to accept the other IRB's review. In such cases, the MDCH IRB requires copies of the material submitted to the other IRB, the signed approval form from the other IRB, and the completed and signed MDCH IRB Initial Abbreviated Application. The MDCH IRB reserves the right to question the adequacy of the other institution's IRB review and/or disagree with the other IRB's decision. The MDCH IRB review is binding on any MDCH involvement in the activity.

Some human subject's research may be eligible for exemption, but the MDCH IRB must grant the exemption. This exemption is not an exemption from review, but rather an exemption from the requirements of non-exempt human subject's research, under the provisions of 45 CFR 46.101(b) with the exception of the MDCH requirement in Section 6. In addition to activities that may be eligible for exemption, an expedited approval process can be used for many activities that involve minimal risk. Expedited review does not require consideration and voting by the full IRB committee.

No human subject's research that involves MDCH (as specified in section 1) can begin before the MDCH IRB has reviewed and granted written approval or an exemption. Under MDCH's Federal Wide Assurance and 45 CFR 46.112, no institutional office or official may approve research involving human subjects that has not been approved by the MDCH IRB.

2. Health Insurance Portability and Accountability Act (HIPAA) Privacy Board

The MDCH IRB serves as the Health Insurance Portability and Accountability Act (HIPAA) privacy board to review requests for a waiver of authorization to use protected health information for research purposes.

3. Scientific Misconduct

The MDCH IRB may be asked by the Department's Research Integrity Officer to participate in the inquiry and investigation of allegations of scientific misconduct as provided for in the Department's Policy and Procedures for Responding to Allegations of Scientific Misconduct.

4. MDCH IRB Membership and Confidentiality

A. Membership

Members of the MDCH IRB are appointed by the Director to represent the following MDCH administrative units that may engage in human subject's research: Mental Health and Substance Abuse Administration, Medical Services Administration, Public

Health Administration, Health Policy and Regulation Administration. In addition at least one person not affiliated with MDCH shall be appointed. The MDCH Director has designated the Chief Medical Executive as the Signatory Official for the MDCH IRB. There is a full-time employee allocated for the IRB administrator position and a full-time employee allocated for the IRB secretary position. The IRB administrator will also be the MDCH IRB chair. The IRB chair/administrator will be evaluated by his/her direct supervisor in consultation with the Institutional Official. The IRB administrator is designated by the Institutional Official (the Director of MDCH) for correspondence with the Office for Human Research Protections (OHRP) and/or the Food and Drug Administration (FDA).

B. Confidentiality

All IRB members and staff shall sign the IRB confidentiality form. Any guests at an IRB meeting shall sign the IRB confidentiality form at each meeting. Certain IRB records are confidential. These include the identity of specific members during deliberations and votes, personal information about study subjects and certain proprietary information in IRB applications and other materials. The confidentiality of IRB members is important to protect members from undue influence in their deliberations and votes. Protection of subject's personal information is important so that unexpected problems and adverse events can be reported and investigated, while maintaining confidentiality. Information in IRB applications can include proprietary and other information that needs to be protected for the integrity of the study and right of the investigator to protect their intellectual property.

5. IRB Review of Activities that Could Be Human Subject's Research

It is the responsibility of each MDCH Bureau or Office Director to assure that a member of the MDCH IRB is consulted on any project in his or her jurisdiction that may involve human subject's research. If the IRB member determines that the activity could be human subject's research then the "MDCH IRB Review Application" ([Form #DCH-1277](#)) shall be completed and submitted. This form is included in the attachments.

6. Procedures for Exempting Research

Whenever human subjects are involved in an activity that involves the collection and analysis of data designed to develop or contribute to new knowledge, the MDCH IRB shall make an official determination of the need for IRB review. The determination could be that the activity is not human subject's research, but only the IRB, or an IRB member, should make this determination. This is important because the definition of research is not precise and the MDCH IRB is required to ensure that any potential involvement of human subjects in research is not undertaken without review.

Some human subject's research is eligible for exemption under the provisions of [45 CFR 46.101\(b\)](#). This is an exemption from the requirements of non-exempt human subject's research and is not an exemption from initial MDCH IRB review. Only the MDCH IRB

can grant this exemption. This decision can be made by the chair or delegated to a committee member for a recommendation that the chair would sign, if he or she agrees with the recommendation. In such cases, the IRB records shall document the provisions of [46.101\(b\)](#) that allow the exemption. Once the chair has granted an exemption, the approval form will be completed and signed by the chair and the study material will be filed and distributed as described in Section 9.

Some activities are either research that does not involve human subjects or analyses that are not done for research. Activities that clearly do not involve human subjects do not require IRB review. If there is any question whether human subjects are involved or if the activity is research, the researcher is expected to consult a member of the MDCH IRB. A memo from a MDCH IRB member that the activity is not human subject's research constitutes documentation that the activity does not need IRB review.

MDCH engages in many activities that involve the systematic collection or analysis of data from or about living persons. Many of these activities are done for the purpose of program evaluation. When the purpose of such activities is to assess the success of an **established** program, and the information gained from the evaluation will be used to improve that program, the activity may not have to be considered research. When an activity is undertaken to test a **new, modified, or previously untested intervention, service, or program** to determine whether it is effective and can be used elsewhere, the activity may be research and subject to IRB oversight (if it involves human subjects).

Some data collection and analyses are done for public health surveillance. The MDCH IRB should be consulted for any **new** projects that may be classified as public health surveillance. Established public health surveillance systems do not require MDCH IRB review.

Another consideration that should prompt IRB review is if data are collected from or about individuals that is not for their direct benefit. For example, data that are required for participation in a program do not need IRB review, but when clients of a program are asked to provide information that is not required for their participation, IRB review may be needed. In such cases, an IRB member should be consulted. Ethical review may be appropriate even if not required by IRB regulations.

Activities that have been determined by the MDCH IRB to be research that does not involve human subjects or not to be research (i.e. surveillance and program evaluation) do not require further IRB review unless they are modified in a manner that could result in the activity becoming human subject's research.

A research project that is determined by the IRB to meet the criteria for exempt status does not need further IRB review with some exceptions. The investigator is required to report to the IRB any revision in the research activity that could cause the research to change from exempt to non-exempt status. The investigator is also required to report to the IRB any unexpected problems/adverse events that present a risk to subjects or to others. When the research project is completed, the investigator is required to notify the

IRB. The exempt status expires when the research project is completed (closed) or when the review category changes as described above.

Research that is determined to be exempt is not exempt from the protection of the human subjects. The following criteria to protect human subjects are required for an exempt determination:

- The investigator assures that human subjects will voluntarily consent to participate in the research when appropriate (e.g. surveys, interviews, interactions with subjects) and will provide subjects with pertinent information, e.g. the activity involves research, a description of procedures, that participation is voluntary, name and contact information for the investigator, subjects can withdraw at any time, and risks and benefits;
- The investigator assures that human subjects will be selected equitably, so that the risks and benefits of the research are justly distributed;
- The investigator assures that the IRB will be immediately informed of any unexpected problems/adverse events that would increase the risk to the human subjects or others, or changes that would make the category of review no longer exempt;
- The investigator assures the IRB will be immediately informed of any incidents or complaints from subjects regarding their risks and benefits; and
- The investigator assures that confidentiality and privacy of the subjects and the research data will be maintained appropriately to ensure minimal risk to subjects.

7. Procedures for Initial Review of Nonexempt Research

The director of a MDCH Bureau or Office that is involved in any research involving human subjects (as defined in the first section of this document) shall see that the research is submitted for IRB review and shall be responsible for compliance with MDCH IRB requirements. The MDCH Bureau or Office director may designate or allow an MDCH employee from their jurisdiction to be the Responsible MDCH Employee. The Responsible MDCH Employee should be familiar with the research and can sign the MDCH IRB Review Application for the MDCH Bureau or Office director.

MDCH IRB requires submission of the MDCH IRB Review Application form, or the Initial Abbreviated Application form, when another IRB's application is used, in order to review activities that may involve human subject's research. The application form (in Word format) is designed so that only those sections that apply to the particular activity need to be completed. The form also indicates the additional documents that are required to accompany this application form, such as informed consent documents, study protocols, survey instruments, etc. The form may be obtained from the IRB secretary at the addresses or phone number listed below or from www.michigan.gov/irb.

The required material should be submitted to:

MDCH IRB
7th Floor, Capitol View Building,
201 Townsend Street, Lansing, MI 48913

Phone 517-241-1928
Fax 517-355-8297
MDCH-IRB@michigan.gov

The name of the “Responsible MDCH Employee” must be indicated on page one of the MDCH IRB Review Application form and that employee must also sign the MDCH IRB Review Application form where indicated or send the application from their MDCH email account. This should be the Bureau or Office director or the person who has the most direct MDCH involvement in the activity. His or her signature is to assure adherence to MDCH IRB requirements for the protection of human subjects. This person shall be responsible for all correspondence between the MDCH IRB and other study investigators or personnel.

In addition to the application material, the "Responsible MDCH Employee" must have documented IRB-approved training. MDCH training is the CITI online training course or an approved in-person training provided by the MDCH IRB. One can also submit documentation of IRB-approved training from another institution for consideration. Approved training is valid for three years.

It is strongly recommended that all other MDCH employees and anyone else engaged in human subject's research involving MDCH, complete IRB-approved training. The “Responsible MDCH Employee” shall determine who requires training and see that they have IRB training appropriate to their role in the research.

The MDCH IRB office will do an initial review to determine if the required material has been submitted and to recommend the type of review. In many cases, the activity will be eligible for exemption or expedited approval.

A. Expedited Review

Expedited review can only be done for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. **MINIMAL RISK means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR 46.102(i)).** A determination of the level of risk will be based upon 45 CFR 46.102(i) using the general population rather than any particular population to define minimal risk. It can be used to review either or both of the following:

- 1) Some or all of the research appearing on the list of categories (attached) the Secretary of HHS has published in the Federal Register (63 FR 60364-60367, November 9, 1998) that meets the criteria for minimal risk, as determined by the reviewer(s). The categories listed give examples. Research eligible for expedited review can include other specific activities that otherwise qualify because they are minimal risk and among the categories listed.

- 2) Minor changes in previously approved research during the period for which approval is authorized. Minor changes are those that do not involve any potential increase in risk to subjects.

In such cases, the chair may grant approval, or ask other committee members to review the proposal and make recommendations. Committee members who have had at least six months active experience on an IRB are eligible to perform expedited reviews. Active experience includes attending at least six full committee meetings or participating as a “shadow” reviewer in at least six expedited reviews. Once the chair has granted expedited approval the “Institutional Review Board Approval” ([Form #DCH 1280](#)) will be completed and signed by the chair and the study material will be filed and distributed as described later in Section 9. If a committee member disagrees with a disposition, the proposal will undergo further review by other committee members or the full committee and the Responsible MDCH Employee would be notified to halt activity until further notice.

Approval of minor revisions that involve no increased risk can be documented by email and no official approval form is required.

B. Full Committee Review

All human subjects’ research that involves more than minimal risk must undergo full committee review. In addition, the IRB administrator, the chair, or any committee member can request full committee review if they feel the full committee should be consulted, even if the activity involves only minimal risk. The MDCH IRB has monthly scheduled meetings and can meet on an ad hoc basis if necessary.

In order for a proposal to be considered by the full committee, the study material should be submitted at least 10 working days before the monthly meeting. This is to provide sufficient time to distribute the material to committee members for their review.

A project that requires full committee review can only be approved by a majority of those present at a convened meeting. A convened meeting requires that a majority of the IRB members are present, including at least one member whose primary concerns are in non-scientific areas. No committee member may participate in the initial or continuing review of any project in which the member has a conflicting interest (see Section 18), except to provide information requested by the IRB. When a member with a conflict of interest is recused from a vote, there must be a majority present without this member for a valid vote.

A full committee review will be considered valid only when the requirements of [45 CFR 46.108\(b\)](#) are fully met. A quorum, including one nonscientist, must be present at the time of any official action. Substantive clarifications or modifications of the protocol or informed consent that are directly relevant to the determinations required by the IRB under [45 CFR 46.111](#) require deferral of an IRB decision. A decision for approval can only be made when these modifications have been made and reviewed by the convened

full committee. The chair may approve revisions that the convened IRB determines can be made by simple concurrence of the investigator, under the expedited approval process described above.

C. Criteria for Approval

The MDCH IRB shall review all human subjects' research in which the department is involved as specified on the first page of these procedures. It has the authority to approve, require modifications to secure approval, or disapprove all covered research activities. Unless waived in whole or in part, it shall require that information given to subjects in the informed consent process is in accordance with the requirements of 45 CFR 46.116. It may require that information in addition to that specifically mentioned in this regulation be given to subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects. The IRB shall require documentation of informed consent unless it waives this requirement in accordance with 45 CFR 46.117.

In order to approve research, the IRB shall determine that **all** of the following requirements are satisfied:

- 1) Risks to subjects are minimized:
 - a) by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
 - b) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- 2) Risks to subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research. The IRB should not consider possible long range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.
- 3) Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes of the research and the setting in which the research will be conducted. It should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- 4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative in accordance with, and to the extent required by, 45 CFR 46.116.

- 5) Informed consent will be appropriately documented in accordance with, and to the extent required by, [45 CFR 46.117](#).
- 6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- 7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- 8) The MDCH IRB may also consider potential risks to populations and to moral or cultural norms, in addition to the risks to individual subjects.
- 9) MDCH IRB requires that the most recent approval date be included on the informed consent document and only the most recent version shall be used to obtain consent.

8. Procedures for Continuing Review of Research or Closing a Study

A. Continuing Review

IRB approval can be for a maximum period of one year. Approval may be for a shorter period, but it may not be for more than one year. Prior to the expiration date of the approval, the project must be resubmitted for approval in order for human subject's research to continue. There is no provision for any grace period extending the conduct of research beyond the expiration date of the approval. Review of proposed revisions is not considered to be a continuation review and does not alter the expiration date. IRB continuation review that occurs before 30 days of the expiration of an annual approval date may keep the original one-year renewal date for the next year's continuation review. For example, if the original expiration date is 12/31/03 and the continuation review and approval occurs as soon as 12/01/03, the new expiration date can be 12/31/04.

The requirements for approval that apply to initial review also apply to the continuing review of a previously approved project. In order to approve the continuation of previously approved research, the IRB requires a completed "Application for Continuation" (Form # [DCH 1278](#)) or another IRB's continuation form that includes:

- 1) The number of subjects accrued,
- 2) A summary of any adverse events and/or unanticipated problems involving risks to subjects or others,
- 3) A summary of any withdrawal of subjects from the research, or complaints,
- 4) A summary of any recent literature, interim findings, and amendments or modifications that are relevant to the research,

- 5) Any relevant multi-center trial reports from the Data Safety Monitoring Boards or Data Monitoring Committees. (Such study-wide reports may satisfy the requirements of #4 without being directly submitted to the local IRB by the author).
- 6) A copy of the current informed consent document(s) and any newly proposed one(s).

The currently approved or proposed consent document(s) must be reviewed to ensure accuracy and completeness. Any significant new findings that may relate to a subject's willingness to continue in the study must be provided in accordance with HHS regulations [45 CFR 46.116\(b\)\(5\)](#). This requirement applies not only during continuation review but whenever such information is learned.

In addition, [OHRP "Guidance on IRB Continuing Review of Research"](#) will help direct MDCH IRB review for renewal of approved research.

A project that was initially approved by full committee review can only be approved for continuation by full committee review, except for continuing review of research previously approved by the convened IRB as follows:

- 1) Where:
 - a) The research is permanently closed to the enrollment of new subjects;
 - b) All subjects have completed all research-related interventions; and
 - c) The research remains active only for long-term follow-up of subjects; **or**
- 2) Where no subjects have been enrolled and no additional risks have been identified by either the IRB or the investigator at any site or from any other relevant source; **or**
- 3) Where the remaining research activities are limited to data analysis; **or**
- 4) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories for expedited review do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified. The determination that "no additional risks have been identified" does not need to be made by the convened IRB.

The full set of materials from the initial review, any subsequent modifications, and the meeting minutes should be reviewed by the chair, or the chair's designee, and made available to any committee member upon request.

When continuing review of a study does not occur prior to the end of the approval period specified by the IRB, expiration of approval is automatic and the research must stop, unless the IRB determines it is in the best interests of individual subjects to continue participating in the research interventions or interactions. Such a stoppage does not have to be reported to OHRP as a suspension of IRB approval under HHS regulations.

The MDCH IRB requests annual updates of activities that were exempted from IRB approval. The IRB Administrator will annually issue Form [DCH #1279](#) to the Responsible MDCH Employee designated on the original application to request information to ensure the exemption is still appropriate.

B. Closing a Study

The “Annual Update on Activities Exempted by the MDCH IRB” (Form [DCH #1279](#)) and the “Application for Continuation” (Form [#DCH 1278](#)) can be used to report research that has been completed at the time of annual review. Research requires continuing review and approval as long as any research interventions or interactions are taking place or identifiable data are being analyzed. If the research is completed prior to the annual review, and further data analysis will only consist of data that are de-identified the “Responsible MDCH Employee” should send an email to the MDCH IRB notifying them of the date data collection was completed.

9. Procedures for Reporting IRB Findings and Actions to the Responsible MDCH Employee and the Institution

Once the MDCH IRB has approved a project, the approval form will be completed and signed by the chair and the study material will be filed. The signed approval form will be sent at this time to the “Responsible MDCH Employee” and a copy sent to the responsible Bureau or Office director. The “Responsible MDCH Employee” shall communicate with investigators outside of MDCH and provide them copies of IRB correspondence. Copies of approval forms are distributed to committee members at the next monthly meeting.

10. Procedures for Requiring Continuing Review More Often Than Annually

The full IRB committee will designate those projects that need review prior to one year in order to ensure the protection of the rights and welfare of research subjects. The committee will make a subjective judgment on this need that considers such things as studies with considerable risks or complexity, previous IRB noncompliance by investigators or an institution, anticipated changes in the protocol, or anticipated new developments in the field that could be a concern to study subjects.

11. Procedures to Determine Projects That Need Verification From Sources Other Than The Investigator That No Material Changes Have Occurred Since Previous IRB Review

The full IRB committee will designate those projects that need verification from sources other than the investigator that no material changes have occurred since previous IRB

review. The committee will make a subjective judgment on this need that considers such things as studies with considerable risks or complexity, previous IRB noncompliance by investigators or an institution, projects identified or suspected (e.g., from continuing review reports or other sources) where material changes occurred without IRB approval, and anticipated changes in the study or new developments in the field that could be a concern to study subjects. In addition to these criteria, the IRB reserves the right to randomly audit projects to verify that no material changes have occurred in any project since the previous IRB review.

12. Procedures to Ensure Prompt Reporting of Changes in Research Activity

The MDCH IRB must approve any changes to the approved study protocol before they are implemented, except when necessary to eliminate apparent immediate hazards to the subject. This is stated explicitly on the Approval Form, [\(DCH-1280\)](#). This requirement will be included and strongly emphasized in training sessions as well.

Proposed changes shall be reported directly to the IRB chair using the research revision form [DCH-1478](#). Proposed changes must be reviewed and approved at convened meetings according to [45 CFR 46.108\(b\)](#) unless expedited review is appropriate under the provisions of [45 CFR 46.110\(b\)\(2\)](#). The chair will evaluate the proposed changes to determine if they are minor changes that could be approved by expedited review or more substantial changes that require full committee review and approval. The criteria for determining that a revision is minor includes changes in informed consent language that increase or clarify the information provided, changes that involve no increase in risk or imposition on the study subjects, changes that increase the potential or actual benefits to subjects without increasing the potential for undue influence, and certain changes that are only administrative.

In cases that require full committee review, the chair shall determine if the research should be interrupted until such time as the full committee can review and approve the changes. If the research is interrupted, the chair and the MDCH IRB committee shall make every effort to convene and promptly review the changes. In any case, the changes cannot be implemented without the written approval of the MDCH IRB. MDCH IRB reserves the right to randomly audit projects to ensure that protocol changes are not implemented without its prior review and approval.

Revisions to a research protocol should be incorporated into the active protocol document and the latest revision date included in this document on each revised page and the first page of the protocol. Approval of revisions will be documented on the MDCH IRB Approval Form, [\(DCH-1280\)](#). Revisions that involve no increase in risk may be documented by email without using the MDCH IRB Approval Form, [\(DCH-1280\)](#).

13. Procedures to Ensure Prompt Reporting of Problems Involving Risks to Subjects or Others

The MDCH IRB requires that any unexpected problems involving risks to subjects or others, unexpected adverse events or changes in the research environment that could potentially be a human subjects concern must be reported immediately to the MDCH IRB chair. This is explicitly stated in the approval form and is included and strongly emphasized in training sessions as well.

The chair will evaluate the reported problems to determine the gravity of the risk to human subjects or others and the steps that are needed to address the situation. The chair may need to act immediately without convening the IRB to protect human subjects or others. In such cases the chair shall notify the full committee about the problem, the immediate steps that were taken, and convene the full committee as soon as possible to review the situation. The chair shall determine if the research should be interrupted until such time as the full committee has reviewed the facts and agreed on a resolution. The chair shall weigh the risk of interrupting the study against the risk of continuing until the problem is resolved and shall not suspend the research if it results in a greater risk.

14. Procedures to Ensure Prompt Reporting of Noncompliance With 45 CFR Part 46, or IRB Requirements or Determinations

The MDCH IRB application form requires the signature of the Responsible MDCH Employee to assure departmental responsibility for the protection of human research subjects and adherence to MDCH IRB requirements. The MDCH IRB requires the “Responsible MDCH Employee” to immediately report to the MDCH IRB chair any unexpected problems involving risks to subjects or others, unexpected adverse events or changes in the research environment that could potentially be a human subjects concern. This is explicitly stated in the approval form and is included and strongly emphasized in training sessions as well.

As soon as the chair receives such a report, he or she will immediately contact the Responsible MDCH Employee to get more information and take the necessary action as described for “Changes In Research Activity” or “Problems Involving Risks To Subjects or Others” Sections 12 and 13 above. MDCH IRB can randomly audit research to ensure compliance with regulations and MDCH IRB requirements and determinations or to investigate suspected noncompliance. Failure to report noncompliance can result in actions ranging up to termination of the employee, suspension of the research and restriction of future human research activity.

15. Procedures to Ensure Prompt Reporting of Any Suspension or Termination of IRB Approval

Reported or suspected noncompliance with 45 CFR Part 46, or IRB requirements or determinations will be immediately investigated as described above. If the investigation

indicates that the noncompliance constitutes an imminent threat to participants or others, the chair shall issue a letter requiring suspension of the research. In addition to notifying the Responsible MDCH Employee, the chair will notify the signatory official and Director of MDCH, the responsible Bureau or Office director, and the OHRP (if the research is federally sponsored). The MDCH IRB will evaluate the noncompliance and determine what should be done to protect the study participants or others. This could include both steps to protect them from any potential harm that could result from participation that has already occurred and steps to prevent harm if the study is permitted to resume. The MDCH IRB may determine the steps to be taken to allow the study to continue or it may determine that it should be terminated. In addition, the MDCH IRB may find that future participation in research by investigators who were noncompliant will be subject to special scrutiny or restricted entirely.

16. Reporting Responsibilities

The Bureau or Office director is responsible for ensuring that MDCH IRB review occurs for any human subject's research in his or her jurisdiction. This person is responsible for ensuring that they or the Responsible MDCH Employee promptly report to the MDCH IRB chair:

- 1) Any unanticipated problems involving risk to subjects or others and unexpected adverse events, and
- 2) Any serious or continuing noncompliance with 45 CFR 46, 21 CFR 50 and 21 CFR 56 or the requirements or determinations of the IRB.

The MDCH IRB chair is responsible for notifying the Responsible MDCH Employee and the Bureau or Office director responsible for any human subject's research in his or her jurisdiction, of any suspension or termination of IRB approval.

The Bureau or Office director responsible for any human subject's research in his or her jurisdiction shall report any suspension or termination of IRB approval to all investigators and institutions involved in the research.

The MDCH IRB chair is responsible for reporting:

- 1) Unanticipated problems involving risks to subjects or others and unexpected adverse events,
- 2) Serious or continuing noncompliance with 45 CFR 46, 21 CFR 50 and 21 CFR 56 or the requirements or determinations of the IRB, and/or
- 3) Any suspension or termination of IRB approval

to the appropriate Responsible MDCH Employee and the departmental Bureau or Office director who is responsible for the research, the MDCH signatory official and director, any supporting Agency or Department Heads, and OHRP, if federally funded.

17. Range of Possible Actions in Response to Reports of Unanticipated Problems Involving Risks to Subjects, or Others, Unexpected Adverse Events, or of Serious or Continuing Noncompliance

MDCH IRB shall evaluate the unanticipated problem/adverse event or noncompliance and determine if the research should be immediately suspended or if suspension would result in more harm than allowing research to continue until the situation is resolved. The priority will be to immediately take the necessary steps to protect the subjects. Once everything is done in this regard, the IRB will gather evidence to evaluate responsibility and determine what actions are needed to ensure the risk is mitigated and prevent further risk. In the case where there is evidence to indicate responsibility for unanticipated risks, or serious or continuing noncompliance, there are a range of possible actions the IRB can take against the responsible parties. Depending on the seriousness of the issue and the cooperation of the investigators, the actions can range from working with the involved individuals to resolve the current situation to terminating the research and restricting participation in future human research activities involving the department. Scientific misconduct should be reported to the department's Research Integrity Officer.

18. Conflicts of Interest

The MDCH IRB application form requires a description of any potential conflicts of interest. A conflict of interest includes any interest that could, or could be perceived to, compromise the integrity of the study, even if unlikely. The IRB will determine if any such conflicts of interest must be revealed to potential study subjects or if they constitute an unacceptable risk that would require disapproval of the research.

In addition, a MDCH IRB member is not allowed to participate in the initial or continuing review of any project in which he or she has a conflicting interest, except to provide information requested by the IRB. After providing information or answering questions, an IRB member who has a potential conflicting interest shall leave the meeting during any subsequent discussion and voting and this shall be noted in the IRB meeting minutes.

19. IRB Review in Emergency Situations

According to [45 CFR 46.103\(b\)](#) and [46.116\(f\)](#), human subject's research cannot begin, even in an emergency, without prior IRB review and approval. If emergency medical care is initiated without prior IRB review and approval, the patient may not be considered a research subject, the emergency care cannot be considered research, and no data

regarding such care can be included in any report of a prospectively conceived research activity.

20. IRB Records and Documentation

- 1) IRB protocol records must include all the information stipulated by [45 CFR 46.115](#).
- 2) The minutes of IRB meetings must include all the information stipulated by [45 CFR 46.115\(a\)\(2\)](#) including:
 - a) Separate deliberations, actions, and votes for each protocol undergoing initial or continuing review;
 - b) The vote on all IRB actions including the total number of votes broken down by the number of members voting for, against, and abstaining. To protect the confidentiality of the individual IRB members, IRB minutes will not identify individual member's votes or deliberative comments;
- 3) The documentation of findings shall comply with:
 - a) [45 CFR 46.116\(d\)](#) when approval is granted for a consent procedure that does not include, or that alters, some or all of the required elements of informed consent;
 - b) [45 CFR 46.117\(c\)](#) when approval is granted to waive the requirements for signed informed consent;
 - c) [45 CFR 46.204-207](#) when approving research involving pregnant women, human fetuses, or neonates;
 - d) [45 CFR 46.305-306](#) when approving research involving prisoners;
 - e) [45 CFR 46.404-407](#) when approving research involving children;

The minutes of a full committee review shall document protocol-specific information to justify each of the required considerations involved with a) – e) above. The chair is responsible for such documentation when approval is granted by expedited review.

- 4) The documentation of the approval period shall comply with [45 CFR 46.103\(b\)\(4\)](#) and [46.109\(e\)](#). The minutes of a full committee review shall document the approval period. Approval will be for 12 months unless otherwise determined to be less than 12 months. The chair is responsible for such documentation when approval is granted by expedited review.
- 5) The retention of IRB records shall comply with [45 CFR 46.115\(b\)](#) that requires records be kept for at least three years after the completion of the research and that

the records be accessible for inspection and copying by an authorized representative of HHS at reasonable times and in a reasonable manner and shall also comply with the MDCH record retention and disposal policy.

21. Other Federal, State, and Local Laws and Protections

All state and local laws that provide more protection to human research subjects than [45 CFR Part 46](#), specifically are not affected by these regulations under the provisions of [46.101\(f\)](#).

The Michigan Public Health Code grants the Department the power to designate medical research projects under the provisions of [MCL 333.2631-33](#). These provisions provide strong protections for the confidentiality of data and researchers are encouraged to seek such protection when the confidentiality of research data is a concern.

A Certificate of Confidentiality can provide comparable protection at the federal level. The Public Service Act §301(d), 42 [U.S.C.](#) §241(d) allows HHS agencies to grant these certificates to persons engaged in biomedical, behavioral, clinical, or other research. The certificate protects the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals.

Both the federal Certificate of Confidentiality and the Michigan Medical Research Project designation protect subjects from compelled disclosure of identifying information, but do not prevent the disclosure of identifying characteristics of research subjects that is mandated by law. Researchers, therefore, are not prevented from disclosing certain information about research subjects, such as evidence of child abuse or a subject's threatened violence to self or others. MDCH IRB shall require the consent form to clearly indicate this potential when such situations are anticipated.

22. Special Considerations for Research Involving Children, Prisoners, Pregnant Women, Fetuses, or Neonates

The exemptions at [45 CFR 46.101\(b\)](#) do not apply to research involving prisoners.

The exemption at [45 CFR 46.101\(b\)\(2\)](#), for research involving survey, interview procedures, or observation of public behavior does not apply to research involving children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

For research involving pregnant women, fetuses, or neonates, MDCH IRB will adhere to the regulations of [45 CFR 46.201-207](#), Subpart B. For research involving prisoners, MDCH IRB will adhere to the regulations of [45 CFR 46.301-306](#), Subpart C. For research involving children, MDCH IRB will adhere to the regulations of [45 CFR 46.401-409](#), Subpart D.

Attachments

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure¹

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and [21 CFR 56.110](#). The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, or reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review - expedited or convened - utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review; (8) and (9) apply only to continuing review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application ([21 CFR Part 312](#)) is not required. (Note: Research on

marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application ([21 CFR Part 812](#)) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(2\) and \(b\)\(3\)](#). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-

related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

¹ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

² Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. [45 CFR 46.402\(a\)](#). Source: 63 FR 60364-60367, November 9, 1998.

The Michigan Department of Community Health
Institutional Review Board for the Protection of Human Research Subjects
Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913
Phone: 517/241-1928 Fax: 517/335-8297

MDCH IRB REVIEW APPLICATION

Authority: Code of Federal Regulations Title 45 Part 46

Completion of Sections 1-4 is mandatory for all applications. Note: To complete this application, type answers directly into shaded answer areas. To check a box, put your cursor on the box, double click and choose “checked.”

SECTION 1 – PROJECT IDENTIFICATION

(Completion of this section is mandatory)

- 1.1 Title of the Project (title **MUST** be the same on all study documents): _____
- 1.2 “Responsible MDCH Employee” (MDCH employee responsible for the Department’s role in this research. Employee must be a MDCH Civil Service Employee and have MDCH IRB approved training within the past three years.): _____
- 1.3 “Responsible MDCH Employee’s” Signature: (Required to assure departmental responsibility for the protection of human subjects and compliance with MDCH IRB requirements. Documents are also deemed signed, if they are submitted electronically from the MDCH email account of the “Responsible MDCH Employee”):

- 1.4 “Responsible MDCH Employee’s” Agency and Bureau or Office: _____
- 1.5 “Responsible MDCH Employee’s” Bureau or Office Director: _____
- 1.6 Source of Funding (include both the name of funder and type of agency, e.g., CDC-federal, RWJF-private, etc.):

- 1.7 Grant Number (**REQUIRED** for federally funded projects): _____
- 1.8 Project Type (Check all that apply)

- ☐ Direct human subject participation involving interventions (e.g. treatments, procedures, or experimentation.)
- ☐ Direct human subject participation involving interactions (e.g. surveys, interviews, focus groups, observations, etc.)
- ☐ Indirect human subject participation using existing human data or biological specimens, or data or specimens that will be collected for non research purposes.

1.9 Check which FDA-regulated test articles (i.e., investigational drugs, biologics or devices) will be used in this project? (Check all that apply)

- ☐ No test article used
- ☐ Drug or biologic used IND#: _____ Trial Phase: _____
- ☐ Device used IND#: _____ Risk level (significant or insignificant): _____

1.10 What is the projected date to begin this research? _____

1.11 What is the projected date to complete this research? _____

1.12 List any other IRBs that will review this project: _____

1.13 Describe any conflicts of interest that could, or could be perceived to, compromise the integrity of the research, even if unlikely to do so: _____

1.14 Name of Principal Investigator (if not the responsible MDCH employee listed in 1.2): _____

*****END OF SECTION 1*****

SECTION 2 – APPLICATION TYPE

(Completion of this section is mandatory)

2.1 Does the research involve direct human subject participation? ☐ YES ☐ NO

If **YES**, check other sections below that apply to the research. If **NO**, skip to 2.2.

- ☐ Surveys, interviews, focus groups, observations, etc. – **complete also Section 11.**
- ☐ Blood collection – **complete also Section 12.**
- ☐ Tissue collection other than blood; investigational drugs, biologics or devices; approved drugs, biologics or devices; ionizing radiation; organ/tissue/cell transfer; gene transfer – **complete also Section 13.**
- ☐ Genetic analysis – **complete also Section 14.**

2.2 Does the research involve indirect human subject's participation, i.e., project will use EXISTING data or biological specimens or data or specimens to be collected in the future for non research purposes?

☐ YES ☐ NO

If **YES**, complete Sections 1-4 **AND** Section 15.

2.3 Does the research involve both direct & indirect human subject participation?

☐ YES ☐ NO

If **YES**, complete Sections 1-10, any additional sections checked in question 2.1 **AND** Section 15.

*****END OF SECTION 2*****

SECTION 3 – RESEARCH INFORMATION

(Completion of this section is mandatory)

3.1 Provide a concise (*less than 300 words*) summary of the research, including the following information:

FOR RESEARCH THAT INVOLVES DIRECT HUMAN SUBJECT PARTICIPATION

- The age, gender, ethnicity, and race distribution of the study population, including a description of any vulnerable populations
- What will be done with the subjects for research purposes
- How the research records will be linkable in any way to the subjects
- The informed consent process

FOR RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION

- Information on the kind and source of data or biological specimens to be used for research
- What will be done with these data or biological specimens
- Describe how data will be linkable to the persons from whom the data or biological specimens are derived
- The informed consent process

(Type less than 300 word summary here or indicate if summary is attached)

3.2 What documents are you submitting with this application? Check only those that are applicable.

- ☐ Study protocol
- ☐ Informed consent instrument(s)
- ☐ Investigator's brochure, solicitation material(s) for subject recruitment (*specify*): _____
- ☐ Survey instrument(s)
- ☐ HIPPA-compliant request for waiver of authorization
- ☐ IRB application and approval documents from the institution of the principal investigator, if not MDCH
- ☐ Signed copy of Data Use Agreement(s)
- ☐ Other (*specify*): _____

3.3 If you believe that this project qualifies for one of the exemptions in 45 CFR 46.101(b) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>) please indicate here the specific exemption: _____

3.4 If you believe this project is not human subject's research, please explain: _____

*****END OF SECTION 3*****

SECTION 4 – INFORMED CONSENT PROCESS

(Completion of this section is mandatory)

4.1 Check the informed consent process that will be used? Check all that apply.

- ☐ A comprehensive written document, signed by the subject (or their legal representative).
- ☐ A comprehensive written document, that is not signed (justify with criteria in 46.117(c).
- ☐ A short written document that satisfies the criteria in 46.117(b)(2). If this is proposed, describe the process.

- ☐ The assent of children that documents their willingness to participate in research (required from children who are capable of comprehending the nature of the study). If this box is checked, complete also 4.5.
- ☐ Check this box if you are asking not to use one of these standard informed consent processes and complete “4.2” below.

4.2 Check the appropriate box below if you will not use a standard informed consent process or if you do not plan to seek consent, or if you want to request a waiver of HIPAA authorization.

- ☐ Check this box to request to alter or waive informed consent in whole or in part. (The provisions of 46.116 that permit these exceptions must be explained when such exceptions are requested. Please specify what waiver or alteration you are requesting and how your project satisfies each of the criteria in 46.116.) _____
- ☐ Check this box if you are requesting a waiver of authorization to disclose “protected health information” under HIPAA, for research purposes. If yes, please attach a HIPAA-compliant request for waiver of authorization.
- ☐ Check this box if you are requesting a waiver of **SIGNED** consent and justify how your research satisfies the criteria in 46.117(c). _____
- ☐ Check this box if you believe that informed consent is unnecessary because your project can be exempted as explained in 3.3, or you believe it is not human subject’s research as explained in 3.4 of this application.

4.3 Please specify what consent documents are included in this application (including the most current revision date(s)): _____

4.4 Check below who will provide consent to participate in this research. Check all that apply.

- ☐ The adult subject in the research
- ☐ The legal guardian of the subject in the research - explain the circumstances: _____
- ☐ The next-of-kin of an adult subject – specify relationship and explain the circumstances: _____
- ☐ One parent of a child who participates in the research
- ☐ Both parents of a child who participates in the research
- ☐ The assent of a child who participates in the research

4.5 Specify the criteria to be used to determine whether or not assent to participate should be obtained if children are among the research subjects. _____

Consult 45 CFR 46.116 and 46.117 – for guidance on the elements of informed consent.

Information must be presented in a manner that will enable someone to voluntarily decide whether or not to participate in the research. For assistance in preparing informed consent documents, please see “Guidelines for Informed Consent” located on the MDCH website.

The informed consent process requirements are found in 45 CFR 46.116 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116>) and the documentation of informed consent requirements in 45 CFR 46.117 <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117>.

Informed consent is a process to protect the rights of human research subjects and it should not be considered primarily a form to protect the researcher or institution.

*****END OF SECTION 4*****

Sections (5-14) Are For Research That Involves Direct Human Subject Participation

SECTION 5 – CHARACTERISTICS OF HUMAN SUBJECTS

(Leave this section blank only if there is no direct human participation in the research)

- 5.1 What population(s) (e.g. healthy adults, diabetic children, etc.) are involved? _____
- 5.2 How many subjects in each population category will be recruited? _____
- 5.3 What will be the total duration of involvement of a subject in the study? _____
- 5.4 Describe research relevant to certain populations (e.g., pre-natal care, prostate cancer). _____
- 5.5 Provide justification for research limited to a particular age, gender, ethnic or racial group. _____
- 5.6 Check which of the following vulnerable populations may be research subjects? Justify the inclusion of the vulnerable population categories you check below:
- ☐ Children (age <18 years); Justification: _____
- ☐ Mentally compromised or decisionally impaired persons (specify); Justification: _____
- ☐ Women with reproductive potential; Justification: _____
- ☐ Pregnant or lactating women; Justification: _____
- ☐ Fetuses (*ex utero*); Justification: _____
- ☐ *In-vitro* fertilization; Justification: _____
- ☐ Prisoners; Justification: _____
- 5.7 Check which of the following populations, that could be subject to undue influence or coercion, may be among the subjects. Justify the inclusion of the research subjects listed below who could be subject to undue influence or coercion:
- ☐ Economically or educationally deprived; Justification: _____
- ☐ Patients of the investigator; Justification: _____
- ☐ Students of the investigator; Justification: _____
- ☐ Employees of the investigator; Justification: _____
- 5.8 What are the criteria for inclusion, and exclusion, of research subjects? _____

*****END OF SECTION 5*****

SECTION 6 – SUBJECT RECRUITMENT PROCEDURES

(Leave this section blank only if there is no direct human participation in the research).

- 6.1 How will potential research subjects be identified for recruitment? (e.g., from an existing list, randomly, etc.) _____
- 6.2 Where (e.g., at home, in a clinic) will the potential research subjects be recruited? _____
- 6.3 How (e.g., phone call, brochure, letter) will the potential research subjects be recruited? _____
- 6.4 If recruitment materials are to be used, are they attached?
- ☐ YES ☐ NO
- 6.5 If the research involves a topic that may have specific relevance to certain ethnic, racial, or other groups, what special measures will be taken to optimize recruitment of subjects from these groups?
- _____

*****END OF SECTION 6*****

SECTION 7 – EXPERIMENTAL TREATMENTS and PROCEDURES

(Leave this section blank only if there is no direct human participation in the research).

7.1 Research that involves experimental procedures requires MDCH IRB approval of the study protocol.

The protocol document shall bear a date, and a title matching the title shown in this application. It should describe goals of the study, background information, specific aims, experimental design, statistical analysis of results, subjects of the research, risks and benefits of treatment or procedures, and significance of the outcomes.

Is the study protocol attached? ☐ YES ☐ NO

7.2 Describe any subject compensation. _____

7.3 Describe (non survey) research treatment/procedures. _____

7.4 Will the subjects be interviewed, complete survey instruments, or attend group meetings for the purposes of this research?

☐ YES ☐ NO

If YES, you must also complete Section 11.

7.5 Will blood be taken from the subjects for the purposes of this research?

☐ YES ☐ NO

If YES, you must also complete Section 12.

7.6 Please state whether any of the following will apply for the purposes of this research:

Biological specimens (other than blood) will be taken from the subjects; investigational, FDA-exempted drugs, biologics, or devices or FDA-approved drugs, biologics, or devices will be administered or applied to the subjects; organs, tissues or cells from other humans will be administered or applied to the subjects; subjects will be exposed to ionizing radiation; or genetic material will be transferred to subjects in the course of the research.

☐ YES ☐ NO

If YES, to any of the questions above, provide information by completing the applicable parts of Section 13.

7.7 Will genetic analysis be performed on any biological specimen to be acquired in conjunction with this research?

☐ YES ☐ NO

If YES, you must also complete Section 14.

*****END OF SECTION 7*****

SECTION 8 – RISKS AND BENEFITS OF THE RESEARCH

(Leave this section blank only if there is no direct human participation in the research).

8.1 To indicate your judgment of the overall research-related risk of harm to subjects, choose ONE of the three levels below

- ☐ Minimal risk*
- ☐ Moderate risk
- ☐ High risk

*Minimal risk is considered risk where the probability and magnitude of harm or discomfort anticipated in the research is not greater, in and of itself, than risks ordinarily encountered in daily life of the general population or during the performance of routine physical or psychological examinations or tests.

- 8.2 What direct risks could subjects face by participating in this research, and what measures will be taken to minimize each risk? _____
- 8.3 If “vulnerable populations” or populations susceptible to undue influence or coercion are among the research subjects, what additional measures will be taken to minimize risks that may affect them? _____
- 8.4 What indirect risks (if any) to the public or community could result from this research? _____
- 8.5 What potential direct benefits (if any) could this research provide subjects? _____
- 8.6 What potential indirect benefits (if any) could this research provide the public or others? _____

*****END OF SECTION 8*****

SECTION 9 – RESEARCH RECORDS

(Leave this section blank only if there is no direct human participation in the research).

- 9.1 Will research records be linkable to the subjects by any identifiers, including names, registration numbers, code numbers, etc.?
- ☐ YES ☐ NO (If NO, skip to 9.3)
- 9.2 If information in the research records was revealed, could it place the subjects (or others) at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation?
- ☐ YES ☐ NO
- 9.3 Describe the procedures that will be taken to ensure the privacy of the subjects and to preserve the confidentiality of data, including any plans to seek a “Certificate of Confidentiality” or “Director’s Medical Research Project” designation. (Privacy is the right of an individual to control his or her personal information whereas confidentiality is the obligation of the researcher to protect data they obtain. Note on Confidentiality: Confidentiality in the use of data requires at a minimum: (a) not including personal identifiers such as names, addresses, telephone numbers, e-mail addresses, or Social Security Numbers except when essential to the research; (b) removing personal identifiers at the earliest stage of the research compatible with the study goals; (c) If personal identifiers must remain (e.g. to link with future data), these should be limited to codes that are not based on identifying information and they should be encrypted and (d) the data files should be kept in a secure environment such as a locked cabinet or a properly secured computer file with password protection.)
- Please explain thoroughly: _____
- 9.4 Describe when and how subject identifiers will be destroyed. _____

*****END OF SECTION 9*****

SECTION 10 – COSTS OF THE RESEARCH

(Leave this section blank only if there is no direct human participation in the research).

- 10.1 Describe any and all costs that the subject could incur by their participation, including indirect costs such as costs to their insurance. _____

*****END OF SECTION 10*****

SECTION 11 – INTERVIEWS, SURVEY OR GROUP MEETINGS INVOLVING THE RESEARCH SUBJECTS

(Complete this section if your answer to Question 7.4 was “Yes”).

- 11.1 Describe the methods that will be used to collect information relevant to this section. _____
- 11.2 What is the anticipated duration and number of sessions to collect this information? _____
- 11.3 Describe the information that will be collected by interview, survey, or group meetings. _____
- 11.4 Will the information that will be collected by interview, survey, or group meetings include sensitive information such as substance use, illegal activities, etc.?
☐ YES ☐ NO
- 11.5 If information will be collected by telephone, describe the consent process. _____
- 11.6 How will the privacy of the subjects be protected while collecting information? _____
- 11.7 Could revelation of collected information place the subject, or others, at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation?
☐ YES ☐ NO
- 11.8 How will the information be recorded? Check all that apply.
☐ Text entered by investigators
☐ Text entered by the subject
☐ Voice of the subject
☐ Image of the subject
☐ Other (specify): _____
- 11.9 Describe how any survey records (instruments, recordings, etc.) will be labeled or identified to provide a direct or indirect link to the subject. _____
- 11.10 Are survey instruments and letters of prior announcement of intent to contact attached?
☐ YES ☐ NO

*****END OF SECTION 11*****

SECTION 12 – BLOOD TO BE TAKEN FROM SUBJECTS FOR THE PURPOSES OF RESEARCH

(Complete this section if your answer to Question 7.5 was “Yes”, otherwise leave blank.)

If genetic information is to be obtained from the blood, you must also complete section 14.

- 12.1 Describe how blood (e.g., venipuncture) will be obtained for the purposes of this research? _____
- 12.2 State the number of times, the intervals, and the time-span over which blood will be collected? _____
- 12.3 What is the largest volume of blood to be taken from a subject during a single draw? _____
- 12.4 What is the total volume of blood to be taken from a subject during the entire project? _____
- 12.5 Describe the subject’s right to financial benefit from research using his or her blood. _____
- 12.6 Describe the process for disposal of blood specimens, including all rights of the subject and obligations of the researcher, if there are plans to store the material for future use. _____

*****END OF SECTION 12*****

SECTION 13 – TISSUE TO BE TAKEN OTHER THAN BLOOD; INVESTIGATIONAL, FDA-EXEMPTED DRUGS, BIOLOGICS OR DEVICES; FDA-APPROVED, NON-INVESTIGATIONAL DRUGS, BIOLOGICS OR DEVICES; EXPOSURE TO IONIZING RADIATION; ORGANS, TISSUE OR CELLS TO BE ADMINISTERED; GENETIC MATERIAL TO BE TRANSFERRED

(Complete this section only if your answer to Question 7.6 was “Yes”).

- 13.1 Provide any additional information appropriate for the special considerations of “Research that is infrequently sponsored by the MDCH.” The special considerations for these types of research are discussed in Section 13 of the “Information and Instructions Regarding Research Approval” document, under ‘RESEARCH WITH DIRECT INVOLVEMENT OF HUMAN SUBJECTS.’ _____

*****END OF SECTION 13*****

SECTION 14 – GENETIC ANALYSIS OF BIOLOGICAL SPECIMENS TO BE OBTAINED FROM RESEARCH SUBJECTS

(Complete this section if your answer to Question 7.7 was “YES.”)

- 14.1 Describe the biological specimens that will be genetically analyzed. _____
- 14.2 What particular genetic information will be acquired? _____
- 14.3 What is the specific purpose of the genetic analysis? _____
- 14.4 Describe any potential risk the genetic information could pose e.g., to insurability, employability, or social esteem of the subject, or others. _____
- 14.5 Describe how any genetic information and material will be kept confidential and secure. _____
- 14.6 Describe the process for providing genetic information to the subject (include e.g., the option to know or not to know the results, circumstances involving genetic abnormalities or parenthood, and circumstances that constitute a moral obligation to inform the subject). _____
- 14.7 Describe the circumstances involving any provision for genetic counseling. _____
- 14.8 Describe the subject’s right to any potential financial benefit that may result from research using his or her genetic material. _____
- 14.9.1 Describe the process for disposal of the biological material, including the rights of the subject and obligations of the researcher, if there are plans to store the material for future use. _____

*****END OF SECTION 14*****

END OF SECTIONS FOR RESEARCH WITH DIRECT INVOLVEMENT OF HUMAN SUBJECTS

SECTION 15 – RESEARCH THAT DOES NOT INVOLVE DIRECT HUMAN SUBJECT PARTICIPATION

Complete this section for research that uses: a) existing human data or biological specimens or b) human data or biological material that will be collected in the future for non research purposes.

(Please note that if the research involves both direct human subject participation and also a component that does not involve direct human subject participation, you must complete both the appropriate sections of 5-14 and section 15).

- 15.1 State why and how the existing data or biological materials were collected, or how data or biological materials that will be used in this research will be collected for non research purposes. _____
- 15.2 Were the existing data or specimens originally stored in a way that could reveal the identity of the person from whom the material originated?
- ☐ YES ☐ NO (If **NO** skip to the checklist on page 10).
- 15.3 Will the research records carry any identifiers that could link the information to the person from whom the material originated?
- ☐ YES ☐ NO (If **NO** skip to the checklist on page 10).
- 15.4 What type of data and/or biological specimens will be used for research? _____
- 15.5 From how many persons did/will the data or biological specimens originate? _____
- 15.6 From what source(s) will the data or biological specimens be procured? _____
- 15.7 How will the investigators gain access to the data or biological specimens? _____
- 15.8 If the data or biological specimens were originally collected for non research purposes, have the persons from whom the material originated agreed that the material might also be used for research purposes?
- ☐ YES ☐ NO
- 15.9 Does use of the data or biological specimens involve information which, if revealed, could place someone at risk of criminal or civil liability, or be damaging to their financial standing, employability, or reputation?
- ☐ YES ☐ NO
- 15.10 How will the permission of the persons from whom the data or biological specimens originated be obtained to use the material for research purposes? If permission will not be sought, please justify using specimens without permission. _____
- 15.11 What measures will be taken to keep the research records confidential? _____
- 15.12 Describe when and how subject identifiers will be destroyed. (If this was answered in 9.4 you may skip this question.) _____
- 15.13 Describe any access that researchers will have to information that is not essential to the research, what will be done with this non-essential information, and how it will be protected. _____
- 15.14 Could the research to be conducted on the data or biological specimens reveal information of potential benefit to the persons from whom the material originated?
- ☐ YES ☐ NO
- If **YES**, describe plans to inform subjects about their rights: _____
- 15.15 Could the research lead to the development of a commercial product that may bring financial benefit to the investigators and/or the sponsor?
- ☐ YES ☐ NO
- If **YES**, describe plans to inform subjects about their rights: _____
- 15.16 Have you signed a Data Use Agreement with MDCH?

☐ YES ☐ NO

Have you enclosed a copy?

☐ YES ☐ NO (If NO, please provide)

*****END OF SECTION 15*****

MDCH IRB REVIEW REQUEST COMPLETENESS CHECKLIST

Completion of this section is mandatory.

Numbers in parentheses refer to the sections of the application, where the corresponding issues appear. For each item shown in the following list the applicant should check off the cell to the left of each applicable item to indicate that it has been carried out and/or submitted. The column to the right is for MDCH IRB use only.

Investigator Completes		MDCH IRB
<input type="checkbox"/>	Documents are dated to indicate the latest revisions.	
<input type="checkbox"/>	The same project title is on the application, the study protocol and the informed consent documents.	
<input type="checkbox"/>	Name of the “Responsible MDCH Employee” is shown.	
<input type="checkbox"/>	“Responsible MDCH Employee’s” signature requirement met.	
<input type="checkbox"/>	Copies of all project-specific consent instruments submitted (3.2, 4.2)*.	
<input type="checkbox"/>	Date of most recent version of consent document is shown.	
<input type="checkbox"/>	Copies of survey instruments submitted (3.2, 11.9)*.	
<input type="checkbox"/>	Copy of Study Protocol submitted (3.2, 7.1)*.	
<input type="checkbox"/>	Copies of solicitation materials for subject recruitment submitted (3.2, 6.4)*.	
* Indicates these documents are required when these sections of the application form apply		

FOR MDCH IRB OFFICE USE ONLY:

Date Submitted:	
Decision final:	
Notice sent:	

Processed by:	
Review time:	

This form should be submitted electronically to MDCH-IRB@michigan.gov from the email account of the “Responsible MDCH Employee”.

The Department of Community Health is an equal opportunity employer, services and programs provider.

**Michigan Department of Community Health
Institutional Review Board Determination**

Capitol View Building, 7th Floor, 201 Townsend Street, Lansing, MI 48913

Phone: 517/241-1928 Fax: 517/335-8297

Authority: Code of Federal Regulations Title 45 part 46

To: "Responsible MDCH Employee"

From: MDCH IRB Chair/Administrator

CC: MDCH Bureau or Office Director

MDCH IRB Log #:

Date Received:

Study Title:

Investigator(s):

Funding Source(s):

Committee Action/Recommendation:

- ☐ Tabled
- ☐ Not human subjects research*
- ☐ Exempt*
- ☐ Approved by expedited review without modifications
- ☐ Approved by expedited review with modifications*
- ☐ Approved by full committee review without modifications
- ☐ Approved by full committee review with modifications*
- ☐ Disapproved*

***Comments:**

Signature (Chair):

Date Approved:

Expiration Date:**

**Prior to this expiration date, the project must be re-approved in order for human subject's research to continue.

The MDCH IRB must approve any change to this study protocol. Approval must precede implementation, unless the change is necessary to eliminate an apparent immediate hazard to the subject. The Responsible MDCH Employee must see that any unexpected problem or adverse event in the research is reported immediately to the MDCH IRB at (517) 241-1928 or [MDCH-IRB@michigan.gov](mailto:IRB@michigan.gov)

Michigan Department of Community Health FWA 00007331 IRB00000421

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Michigan Department of Community Health
Application for Continuation of MDCH IRB Approval Form

Authority: Code of Federal Regulations Title 45 part 46

Please provide the following information to request continuation approval of a previously approved activity whose current approval expires: _____

- 1) Title of Research Project** (title must be the same on all study documents): _____
- 2) “Responsible MDCH Employee’s Name”** (MDCH person most directly responsible for the department’s role in the research): _____.

The “Responsible MDCH Employee” is responsible for confirming information on this application with the Principal Investigator when he or she is not an MDCH employee.
- 3) “Responsible MDCH Employee’s Signature”** (Required on the printed copies of this application to assure departmental responsibility for the protection of human subjects and adherence to MDCH IRB requirements. Submission of this form from this person’s State of Michigan email account constitutes a signature): _____
- 4) Name of Principal Investigator:** _____
- 5) MDCH IRB Log Number:** _____
- 6) If the data collection is already complete, and data analysis will involve only data that are de-identified, please indicate the date the data collection was completed. If the research data analysis will involve data with identifiers, what is the projected date for completion of this research?** _____
- 7) How many study subjects have been accrued (if applicable)?** _____
- 8) Summarize any adverse events and/or unanticipated problems:** _____
- 9) Summarize any complaints or withdrawal of subjects from the study:** _____
- 10) Summarize any recent literature, interim findings and amendments or modifications that are relevant to the research:** _____
- 11) Summarize any relevant multi-center trial reports from Data Safety Monitoring Boards or Data Monitoring Committees.** (This only applies to multi-center clinical trials. Such study-wide reports may satisfy the requirements of #10 without being directly submitted to the local IRB by the author.)
- 12) Provide a copy of the current informed consent document** (indicate if attached): Attached ☐
- 13) If research involves another institution with an IRB, provide their current expiration of approval date:** _____. Explain if there is none.
- 14) Provide a brief summary of the protocol (less than 300 words) that describes the current status of the research as it relates to the involvement of human subjects (e.g., enrollment closed, subjects have completed all research-related interventions, only long term follow-up remains, etc.).**

**Michigan Department of Community Health
Annual Update on Activities Exempted by the
MDCH IRB**

Authority: Code of Federal Regulations Title 45 part 46

The following activity was reviewed by the MDCH IRB and found to be exempt from either IRB review or approval:

Title:

Date of Last Review:

MDCH IRB Log #:

Responsible MDCH Employee:

Name of the Principal Investigator:

Please provide the following information about this activity:

- 1) Is the activity still ongoing?
- 2) If the activity has been completed what was the date of completion?
- 3) If the activity is still ongoing what is the projected date of completion?
- 4) Have there been any problems associated with the activity that constitute a potential human subjects concern?
- 5) Have there been any modifications in the activity that could change the exempt status of this activity (if yes, or if you need help to determine if a change could affect the exempt status of the activity please consult a MDCH IRB member)?

Please provide the information (by mail or email) above and return by _____ to:

Institutional Review Board for the Protection of Human Research Subjects
Michigan Dept of Community Health
Capitol View Building, 7th Floor
201 Townsend Street
Lansing, MI 48913
517/241-1928
MDCH-IRB@michigan.gov

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**Michigan Department of Community Health
Institutional Review Board
Research Revision Form**

Authority: Code of Federal Regulations Title 45 part 46

Date: _____

Responsible MDCH Employee: _____

Study Title: _____

Contact email address: _____

MDCH IRB Log # : _____

Directions:

1. Explain the change(s) that you want to make in the approved study.

2. Justify the change(s).

3. Explain whether in your judgment the proposed change materially effects:

(a) the level of risk to the subjects _____(YES) _____(NO), or

(b) the ratio of the benefits to the risks of the study _____(YES) _____(NO).

4. In your judgment does the change(s) warrant a new consent form?

_____ (YES) _____ (NO)

If YES,

(a) attach a new consent form and clearly indicate the changes therein

(b) indicate if previously enrolled subjects should be reconsented?

_____ (YES) _____ (NO)

Use this form to request approval of any revisions to the research. Please email the completed form to
MDCH-IRB@michigan.gov

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